

Remarks

Applicants note that the claims as originally filed were incorrectly numbered as 1, 2, 3, 4, 5, 6, **5, 6**, 7, 8, 9, 10, 11 and 12 – *i.e.*, there are two claims labeled as claim 5 and two claims labeled as claim 6. Applicants have corrected this error such that the following claim numbers have changed:

<u>Original Claim #</u>	<u>Corrected Claim #</u>
claims 1-6	claims 1-6
second claim 5	claim 7
second claim 6	claim 8
claim 7	claim 9
claim 8	claim 10
claim 9	claim 11
claim 10	claim 12
claim 11	claim 13
claim 12	claim 14

Based on the above corrected claim numbers, claims 2, 3, 5, 6, 8, and 10-14 have been amended and claim 9 has been cancelled without prejudice or disclaimer of the encompassed subject matter. The amendments to claims 2, 3, 5, 6, 8, 11 and 14 place the claims in a format more reflective of standard U.S. patent prosecution. The amendment to claim 10 finds support in the specification at, *inter alia*, paragraph [0001] of the published application and in the abstract. The amendments to claims 12 and 13 incorporate the process language of claim 11 as directed to claim 1 and claim 4, respectively. Applicants submit that no prohibited new matter has been added by any of the amendments.

1. Claim Objection

Claim 12 (now, claim 14 as corrected) is objected to as being of improper multiple dependency.

Applicants have amended claim 14 to depend from claim 12 or claim 13 (formerly, claims 10 and 11). Claim 12 depends from independent claim 1 and claim 13 depends from independent claim 4. Applicants therefore submit that claim 14 as amended shows proper multiple dependence.

2. Rejection under 37 C.F.R. 112, second paragraph

A. Claims 9-12

Claims 9-12 (now, claims 11-14 as corrected) are rejected for being unclear to which process is being claimed and for what form.

Applicants have amended claim 12 (formerly, claim 10) to depend from claim 1, while claim 13 (formerly, claim 11) has been amended to depend from claim 4. In view of the clarifying amendments, Applicants respectfully request that this rejection be withdrawn.

B. Claim 7

Claim 7 (now, claim 9 as corrected) is rejected for being unclear because it does not set forth any steps involved in the recited method/process.

Claim 9 has been cancelled without prejudice or disclaimer of the encompassed subject matter, thereby effectively mooted this rejection.

3. Rejection under 37 C.F.R. 112, first paragraph

Claim 8 (now, claim 10 as corrected) is rejected as allegedly lacking enablement because the Examiner asserts that while the specification is enabling for treating type 2 diabetes and lowering blood cholesterol, it does not enable all diseases treated by the recited mode of action.

Without addressing the merits of the Examiner's rejection and in an effort to expedite prosecution of the subject application, Applicants have amended claim 10 to recite the conditions/biological functions identified by the Examiner as enabled by the specification – *i.e.*, the treatment of type 2 diabetes and the lowering of blood cholesterol levels.

Hypercholesterolemia, hyperlipoproteinemia and atherosclerosis, which find support in the specification at, *inter alia*, paragraph [0001] of the published application and in the abstract, are

representative of conditions which are effectively treated by lowering blood cholesterol. In view of the amendments to claim 10, Applicants respectfully request that this rejection be withdrawn.

4. Rejection under 35 U.S.C. 101

Claim 7 (now, claim 9 as corrected) is rejected as not being a proper process claim due to an asserted lack of any steps involved in the process.

Claim 9 has been cancelled without prejudice or disclaimer of the encompassed subject matter, thereby effectively mooting this rejection.

5. Rejection under 35 U.S.C. 102(b)

Claims 1-12 (now, claims 1-14 as corrected) are rejected as allegedly anticipated by WO 01/60804 to Taylor *et al.* (“Taylor”) based on the Examiner’s assertion that Taylor teaches a crystalline form of rosuvastatin with tris(hydroxy)methyl amine.

Applicants submit that the claims of the subject application are directed to novel crystalline forms of the tris(hydroxymethyl)ammonium salt of (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl]-(3R,5S)-3,5-dihydroxyhept-6-enoic acid. The new forms disclosed in the subject application (Form 2 and Form 3) are defined by their X-ray powder diffraction patterns. For example, the form claimed in claim 1 (Form 2) has specific peaks at 2-theta = 3.2, 6.3, 9.5 and 11.0, and the form claimed in claim 4 (Form 3) has specific peaks at 2-theta = 6.9 and 13.1. The full X-ray diffraction patterns for these forms are set out in Figure 1 (Form 2) and Figure 2 (Form 3).

In contrast, the crystalline tris(hydroxymethyl)ammonium salt of (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl]-(3R,5S)-3,5-dihydroxyhept-6-enoic acid described in Taylor is not the same as either of the crystalline forms (Form 2 and Form 3) claimed in the subject application. The crystalline form described in Taylor is defined by its X-ray powder diffraction pattern. The Examiner is directed to Figure 5 of Taylor, which is the X-ray powder diffraction pattern for the salt prepared in Example 2 and the X-ray powder diffraction pattern described on page 3 of Taylor, in the paragraph labeled as (5). A comparison between the X-ray powder diffraction patterns of Taylor and those of the

subject application representing Forms 2 and 3 demonstrates the lack of overlap between the Taylor crystalline form and the crystalline forms of Form 2 and Form 3. For example, the Taylor pattern, with peaks at 7.9, 8.5, 10.2, 16.7, 18.4, 19.3, 19.8, 20.2, 21.5 and 24.9, does not show the peaks at 3.2, 6.3, 9.5 or 11.0 that appear in the Form 2 pattern. Similarly, the Taylor pattern does not show the peaks at 6.9 and 13.1 that appear in the Form 3 pattern. Therefore, Applicants submit that the crystalline forms claimed in the subject application are novel over Taylor and accordingly respectfully request that this rejection be withdrawn.

Further, because there is no teaching in Taylor as to the existence of other crystalline forms of the tris(hydroxymethyl)ammonium salt of (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl]-(3R,5S)-3,5-dihydroxyhept-6-enoic acid or how such forms might be prepared, a person of ordinary skill in the art would have no rationale for attempting to prepare any of these additional crystalline forms. Accordingly, Applicants submit that the crystalline forms claimed in the subject application are also nonobvious over Taylor.

6. Conclusion

Applicants respectfully request allowance of the pending claims in view of the above amendments and remarks. If helpful to further prosecution of the subject application, the Examiner is invited to telephone the undersigned.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

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